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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/086,912	02/28/2002	Robert D.P. Hei	163.1440USU1	1677

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EXAMINER

PUTTLITZ, KARL J

ART UNIT	PAPER NUMBER
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1621

DATE MAILED: 07/11/2003

6

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/086,912

Applicant(s)

HEI ET AL.

Examiner

Karl J. Puttlitz

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on 28 February 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☐ Claim(s) 1-29 is/are pending in the application.
- 4a) Of the above claim(s) 9-29 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) 1-8 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) 1-29 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 5.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-8, drawn to a "stabilized ester peroxycarboxylic acid composition" classified in class 560 subclass 002.
- II. Claims 9-29 drawn to "a method of reducing population of microorganism on an object" classified in class 510 subclass 108+.

Inventions I and II are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case The process can be used with another materially different product, e.g. antiseptic solutions.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper. Additionally, because these inventions are distinct for the reasons given above and the search required for Group I is not required for Group II, restriction for examination purposes as indicated is proper.

During a telephone conversation with Mark Skoog on July 7, 2003 a provisional election was made with traverse to prosecute the invention of I claims 1-8. Affirmation of this election must be made by applicant in replying to this Office action. Claims 9-29 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being

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drawn to a non-elected invention. The Examiner notes that Applicants' representative expressly reserved Applicants' right to file one or more divisional applications drawn to the non-elected subject matter.

Information Disclosure Statement

The information disclosure statement filed June 3, 2002 fails to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each U.S. and foreign patent; each publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed. It has been placed in the application file, but the information referred to therein has not been considered.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

The essential inquiry pertaining to this requirement is whether the claims set out and circumscribe a particular subject matter with a reasonable degree of clarity and particularity. Definiteness of claim language must be analyzed, not in a vacuum, but in light of:

(A) The content of the particular application disclosure;

(B) The teachings of the prior art; and

(C) The claim interpretation that would be given by one possessing the ordinary level of skill in the pertinent art at the time the invention was made. See M.P.E.P. § 2173.02.

Claims 1-9 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 recites that the C₂ or higher alcohol is effective for stabilizing the recited ester peroxycarboxylic acid. In addition, claim 1 recites a non-toxic concentration of the C₂ or higher alcohol. However, "effective for stabilizing" is confusing because the specification does not describe how the alcohol stabilizes the ester peroxycarboxylic acid. In addition, the term "non-toxic" is a term of relative degree, and one of ordinary skill would not readily ascertain those concentrations of the C₂ or higher alcohol.

The examiner notes that substituting this term with the relative amounts of alcohol given on page 8, lines 1-6 of the specification, or alternatively, the relative amounts in claim 3, would overcome this rejection.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and

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the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

To establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations.

The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, not in applicant's disclosure. *In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991). See M.P.E.P. § 2143.

Claims 1-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 99/67213 to SOLVAY (WO 213).

The invention recites, *inter alia*, a stabilized ester peroxydicarboxylic acid composition comprising an ester peroxydicarboxylic acid and C₂ or higher alcohol effective for stabilizing the ester peroxydicarboxylic acid at non-toxic concentration of the C₂ or higher alcohol. The invention also covers those compositions further comprising surfactants and buffers (see claims 4-7). The invention also covers compositions with a pH less than about 4 (see claim 8).

WO 213 teaches an "aqueous monoester peroxydicarboxylic acid solutions ... containing the ester peracid, water, residual amounts of non consumed peroxydicarboxylic compound, one or more diacids, one or more alcohols. See page 5, lines 11-20.

Representative alcohols are "[d]iols containing up to 20 carbon atoms, preferably up to 10 carbon atoms can also be used. Examples of suitable diols are ethylene glycol and *propylene glycol*. Polyols containing up to 20 carbon atoms can also be used.

Examples of suitable polyols include sorbitol and mannitol. [emphasis added]. See paragraph bridging pages 3 and 4.

WO 213 teaches that "[t]he alcohol is generally used in an amount of at least 0,01% wt of the reaction mixture, in particular of at least 2% wt. The amount of alcohol used is usually at most 45% wt. more particularly at most 25% wt Quantities of alcohol from 0,05 to 45% wt are convenient." See page 4, lines 5-11.

Moreover, the "solution of the invention can contain other additives. These additives can be chosen from stabilisers, surfactants and thickeners" In particular, "[t]he surfactants can be nonionic, anionic or amphoteric. Surfctants can be soap or synthetic. Typical examples are described in chapter 2 of Synthetic Detergents by A. Davidson and B/M. Milwidsky, 6.sup.th Edition published in 1978 by George Godwin Limited. Cationic surfactants include quaternary ammonium salts, non-halide examples include sulphates, metosulphates, ethosulphates, hydroxides, acetates, saccharinates, phosphates and propionates. See page 6, lines 30-35.

"The pH of the invention solutions can vary in a wide range. The pH is generally at least -2, most often at least 1. pH values of at most 8 are possible, values of at most 5 are preferred." See page 5, lines 21-23.

Finally, with regard to the recited buffer, adipic acid is added as a mixture of acids in Example 3. See page 8, Example 3.

The difference between WO 213 and the claimed inventions is that WO 213 does not teach the invention with particularity so as to amount to anticipation (See M.P.E.P. § 2131: "[t]he identical invention must be shown in as complete detail as is contained in

the ... claim." *Richardson v. Suzuki Motor Co.*, 868 F.2d 1226, 1236, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989). The elements must be arranged as required by the claim, but this is not an *ipsissimis verbis* test, i.e., identity of terminology is not required. *In re Bond*, 910 F.2d 831, 15 USPQ2d 1566 (Fed. Cir. 1990).). In the context of obviousness, although the claimed invention may be encompassed by WO 213, this by itself render the invention obvious. *In re Baird*, 29 USPQ 2d 1550, 1552 (Fed. Cir. 1994).

However, based on the above, WO 213 teaches the claimed invention with particularity and with a reasonable expectation of success, that the invention would be *prima facie* obvious to one of ordinary skill (the prior art reference teaches or suggests all the claim limitations with a reasonable expectation of success. See See M.P.E. § 2143).

Conclusion

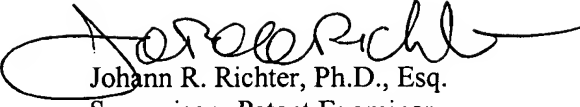
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Karl J. Puttlitz whose telephone number is (703) 306-5821. The examiner can normally be reached on Monday-Friday (alternate).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter can be reached on (703) 308-4532.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

July 9, 2003

Karl J. Puttlitz
Assistant Examiner

A stylized handwritten signature, likely of Karl J. Puttlitz, consisting of a large, looped 'K' and 'P'.A handwritten signature in cursive script, likely of Johann R. Richter, with a large initial 'J' and 'R'.

Johann R. Richter, Ph.D., Esq.
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